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July 1, 2004

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Re: International Application No.: PCT/US2004/009605
International Filing Date: 29 March 2004 (29.03.2004)
Earliest Priority Date: 28 March 2003 (28.03.2003)
Applicant(s): C.R. BARD, INC. ET AL.
Title: IMPROVED BRAIDED MESH CATHETER
Our Reference No.: B1075.70043

CERTIFICATION OF FACSIMILE TRANSMISSION

The undersigned hereby certifies that a Request Under PCT Rule 91.1(b) for Rectification of Obvious Errors with substitute sheet(s) are being facsimile transmitted to European Patent Office, Erhardtstrasse 27, D-80298 Munich, GERMANY, on 1 July 2004.

Colleen F. Sullivan
Name

CFS.
Signature

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IN THE EUROPEAN PATENT OFFICE
AS INTERNATIONAL SEARCHING AUTHORITY

International Application No.	:	PCT/US2004/009605
International Filing Date	:	29 March 2004 (29.03.2004)
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European Patent Office
Erhardtstrasse 27
Munich D-80298
GERMANY

REQUEST UNDER PCT RULE 91.1(b)
FOR RECTIFICATION OF OBVIOUS ERRORS

Transmitted herewith for filing is a Request Under PCT Rule 91.1(b) for Rectification of Obvious Errors with substitute sheets.

If the enclosed papers are considered incomplete, the Authorized Officer is respectfully requested to contact the undersigned collect at (617) 720-3500, Boston, Massachusetts.

Respectfully submitted,

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DOCKET NO.: B1075.70043
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REQUEST UNDER PCT RULE 91.1(b)
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Applicant would like to bring to the Authorized Officer's attention that changes have been made to the above-identified international application.

In the Specification

Page 34, line 3, replace "Figure 22" with --Figure 25-- for clarification;

Page 41, line 23, replace "342" with --310-- to correct an obvious error in reference numerals;

Page 42, line 24, replace "3249" with --362-- to correct an obvious error in reference numerals;

Page 47, line 19, replace "434" with --418-- to correct an obvious error in reference numerals;

In the Drawings

Figure 25, add reference numeral 267 to correct an obvious error in reference numerals;

Figures 30 and 31, delete reference numerals t3 and t4 to correct an obvious error in reference numerals;

Figure 32, add reference numeral 229 to correct an obvious error in reference numerals;

Figures 34A and 34B, delete reference numeral 313 to correct an obvious error in reference numerals;

Figure 41A, add figure labels (Fig. 41B, Fig. 41C, Fig. 41D, Fig. 41E)

Replacement sheets pages 34, 41, 42 and 47 of the specification are enclosed. Replacement sheets of figures 25, 30, 31, 32, 34A, 34B and 41A are also enclosed. Applicant respectfully requests that the replacement sheets and figures be accepted and replace originally filed pages 34, 41, 42 and 47 and figures 25, 30, 31, 32, 34A, 34B and 41A. No new matter has been added.

REMARKS

The Authorized Officer is invited to contact the undersigned by collect telephone call should he/she have any questions concerning this Request.

Respectfully submitted,

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neutral or rest position. As can be seen in Figure 31, each of the balls 214 rests upon the elevated planar rear surface 211 and the friction disk 226 is compressed relative to that shown in Figure 30. As shown best in Figure 25, each of the detents 212 in the planar rear surface 211 may include lead in/lead out sections 267 that are gradually tapered to the level of the planar rear surface 211 to facilitate smooth movement of the balls 214 out of and into the detents 212.

Although the present invention is not limited to the number of detents 212, 215 incorporated into the handle and the thumbwheel, Applicants have found that three detents spaced equally about a circumference of the planar rear surface 211 and the thumbwheel 122 distributes stress evenly about the thumbwheel 122 and permits a sufficient amount of rotation before another detent 212 is encountered. Furthermore, although the present invention is not limited to the amount of force applied to the thumbwheel to change the position of the thumbwheel, Applicants have empirically determined that a force of approximately 4 to 8 pounds is sufficient to resist any forces on the pull cables. Moreover, this amount of force is sufficient so that the thumbwheel cannot be moved inadvertently, and does not require great strength by the user. This amount of force also accounts for any yielding during storage and/or sterilization.

Although this embodiment of the present invention has been described in terms of a plurality of detents in a surface of the handle and a corresponding number of detents that hold a ball or bearing in an undersurface of the thumbwheel, the present invention is not so limited. For example, and as discussed above, the detents in the planar surface 211 of the handle 201 may hold the balls or bearings 214 and not the thumbwheel. Moreover, it should be appreciated that other means of imparting different frictional forces on the thumbwheel may be readily envisioned. For example, rather than detents, the rear planar surface 211 may be contoured to include a plurality of ramps (for example, three ramps). The undersurface of the thumbwheel 122 may include a corresponding plurality of complementary shaped ramps such that when the thumbwheel 122 is in a neutral or rest position, a minimum of friction is imparted, and as the thumbwheel 122 is rotated, the heightened surface of the ramps on the undersurface of the thumbwheel 122 contacts a heightened surface of the ramps in the planar surface. As the thumbwheel 122 is rotated further, addition friction is imparted.

thereof to maintain the distal end of the braided conductive member 28 in a conical shape.

One exemplary process for the assembly of the distal tip portion 302 will now be described. First, the first collet 316a may be secured to the mandrel 306, for example using solder or epoxy. Next, the anchor portion 310 may be slid over the first collet 316a and mandrel 306, and second collet 316b may be secured to the mandrel 306, for example using solder or epoxy. The anchor portion 310, which is secured to collets 316a-b and mandrel 306, may then be inserted into distal cap 308. Anchor portion 310 may be formed by machining, or another suitable process. A chamfer 330 may be provided at the distal end of anchor portion 310 to aid the insertion of anchor portion 310 past the collar 322 of distal cap 308. The individual wires of the braided conductive member 28 may be cut and then separately insulated at their distal ends with an ultraviolet cure adhesive. A potting material may be included between anchor portion 310 and distal cap 308 to secure the distal end of the braided conductive member 28 therebetween.

Because distal tip position 302 may be maneuvered through vasculature and the heart during the course of an electrophysiology procedure, it may be desirable that distal tip portion 302 be constructed so as to reduce trauma to tissue it may contact. Accordingly, Figure 36 illustrates an exemplary embodiment of a portion of catheter 336 having a distal tip portion 338 that includes material selected to provide a gentle interaction with tissue. Distal tip portion 338 comprises a distal cap 340 and an anchor portion 342. Anchor portion 342 is similar to and performs the same function as the anchor portion 310 of Figure 35. Distal cap 340 includes two sub-portions: a proximal portion 340a and a distal portion 340b. Proximal portion 340a is similar to and performs the same function as the distal cap 308 of Figure 35, but includes a protrusion 346 adapted to mate with a recess 344 of distal portion 340b. A bonding agent such as epoxy, or alternate coupling means, may be included in grooves 348 in proximal portion 340a to secure the proximal portion 340a to distal portion 340b. Distal portion 340b may be constructed to provide a more gentle interaction with tissue than occurs with conventional catheter tips. For example, distal portion 340b may be formed of an elastomeric material such as polyurethane or silicone, or another material having a low durometer. Accordingly, distal cap 340 may be used, for example, to locate vein

entrances in the walls of the atria without damaging the tissue of the wall. It should be appreciated that a number of variations are possible for the distal cap portion 340 described above. For example, a unitary cap portion may be formed with the "atraumatic" properties described for the distal portion 340b, or both proximal portion 340a and distal portion 340b may be formed with atraumatic properties. In addition, distal portion 340b can assume a number of different configurations and need not have the shape and dimensions shown in Figure 36.

Referring again to Figure 34A-B, a steering arrangement that may be used in connection with catheter 300 according to another embodiment of the invention will now be described. Steering cables 360 may be provided within catheter 300 to enable the catheter to be bent or curved via actuation of one or more of the steering cables 360. Steering cables 360 may be anchored at steering anchor 362, which is located at a distal end of shaft 304. Actuation of one or more steering cables 360 may cause a bend or curve at a location proximal to steering anchor 362, for example at a junction 364 between distal shaft portion 304a and proximal shaft portion 304b. In one example, distal shaft portion 304a may be formed of a less rigid material than proximal shaft portion 304b so that a bend or curve is formed at a portion of the distal shaft portion 304a near the junction 364 between the distal shaft portion 304a and the proximal shaft portion 304b. As should be appreciated from the foregoing, according to one embodiment of the invention, steering anchor 362 may be provided proximal to braided conductive member 28. Further, a steering "knuckle" (e.g., a location of a bend or curve) may be formed by actuation of a steering cable 360 anchored at steering anchor 362 at a location proximal to the steering anchor.

In the example shown in Figures 34A-34B, steering anchor 362 comprises a plurality of loops formed by steering cables 360 around an exterior surface of catheter 300, wherein the steering cables 360 form a continuous length of cable. The loops may be formed in a recess 366 in the exterior surface of the catheter 300, and may be potted in place and sealed with silicone. In one example, an uncoated section of the steering cables 360 is looped around the catheter shaft 304 two and a half times and then potted to provide sufficient tensile forces for the cables 360.

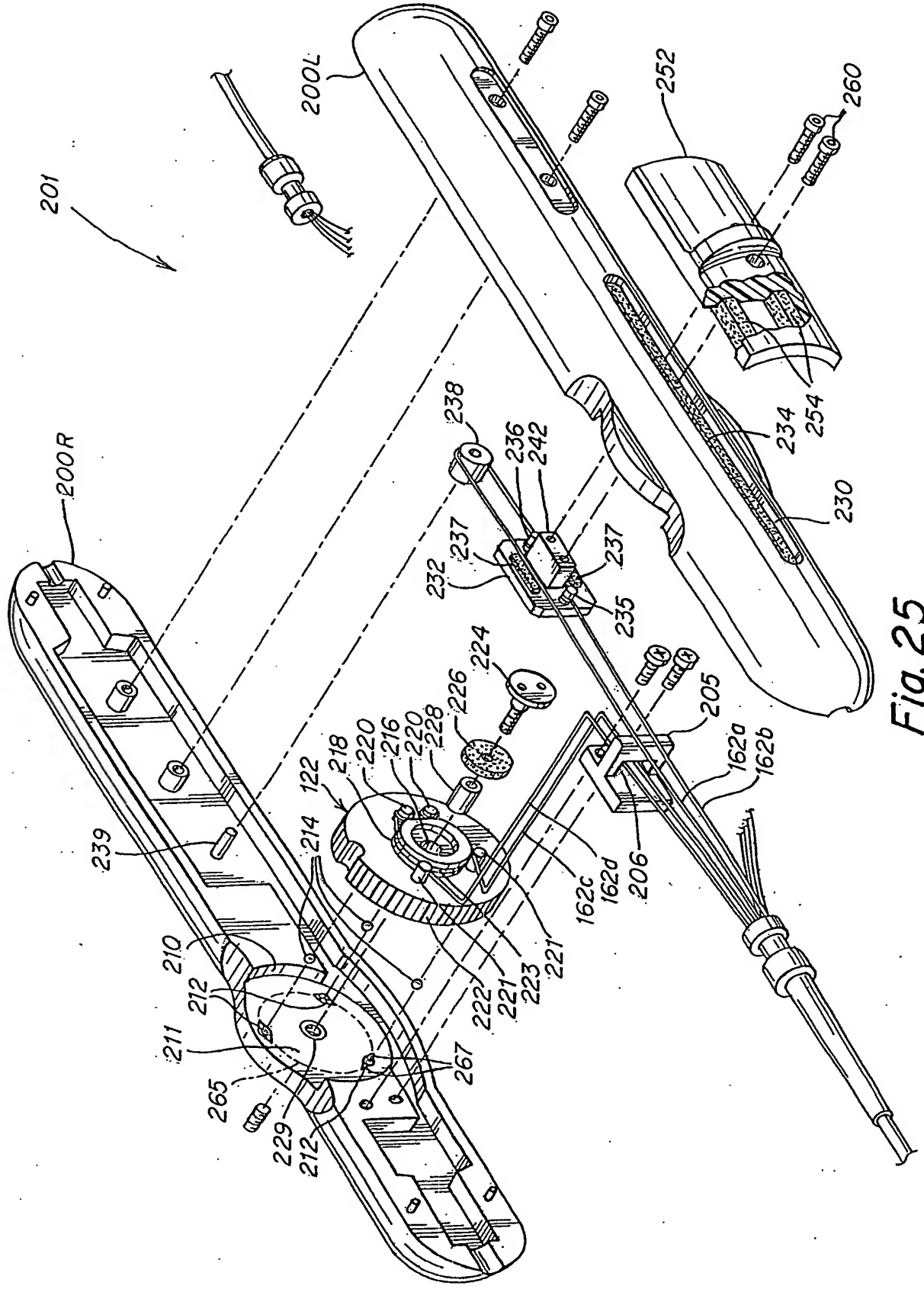
Although the configuration shown in Figures 34A-B provides suitable anchoring of steering cables 360, certain drawbacks exist. For example, an opening is

also be appreciated that the seal 432 described above may have a number of alternate implementations. For example, the seal 432 may be formed of a single element and/or have a shape or configuration other than shown in Figures 41A and 41C.

Steering anchors 430a-b and steering cables 428a-b are configured in a manner similar to those shown in Figure 37. In particular, anchors 430a-b have a width or diameter that is greater than the diameter of steering cables 428a-b. The anchors 430a-b may be integrally formed with the steering cables 428a-b or may be securely attached thereto. Steering cables 428a-b pass through lumens 436a-b, respectively, which extend along at least a portion of catheter 416. Lumens 436a-b respectively include larger width or diameter regions 438a-b and a smaller width or diameter regions 440a-b. Anchors 430a-b may be disposed in larger width or diameter regions 438a-b and may be sized such that the anchors do not fit within smaller width or diameter regions 440a-b. Accordingly, steering cables 428a-b may be anchored at the junction between regions 438a-b and 440a-b, respectively. A bonding agent such as epoxy may be provided to further inhibit movement of the anchors 430a-b.

Figure 41E illustrates an enlarged view of a portion of distal shaft portion 422a, including mandrel 418, steering cables 428a-b, and wires 434 used to form braided conductive member 28. As shown, steering cables 428a-b are disposed in lumens 436a-b formed in the wall of the distal shaft portion 422a. Mandrel 418 is disposed along a central longitudinal axis of shaft 422, and is surrounded by wires 434. The wires 434, which may be braided in the same manner as braided conductive member 28, are disposed in an opening between mandrel 418 and lumens 436a-b. It should be appreciated that the internal configuration of distal shaft portion 422a shown in Figure 41E is merely exemplary, and that other configurations are possible. For example, lumens 436a-b may be absent, and both steering cables 428a-b and wires 434 may be disposed in an opening between mandrel 418 and an outer wall of the catheter shaft 422. In one implementation, steering cables 428a-b may be disposed at an inner radial position with respect to wires 434.

Mandrel 418 extends the length of the catheter 416 to a handle of the catheter. As shown in Figure 41D, distal tip portion 424 includes a distal cap 444 coupled to the mandrel 418 at its most distal end. A distal end of braided conductive mesh 28 is circumferentially disposed about the mandrel 418 in a recess 446 between mandrel 418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122
214
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265
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205
162a
162b
162c
162d
206
221
223
222

Fig. 25

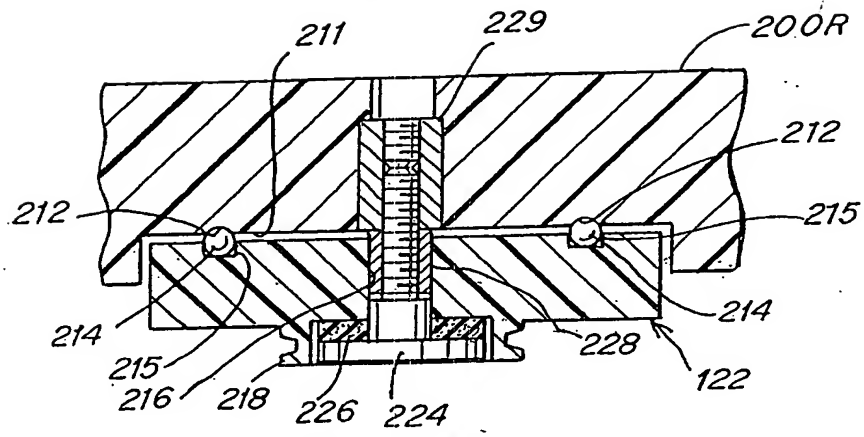
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Fig. 30

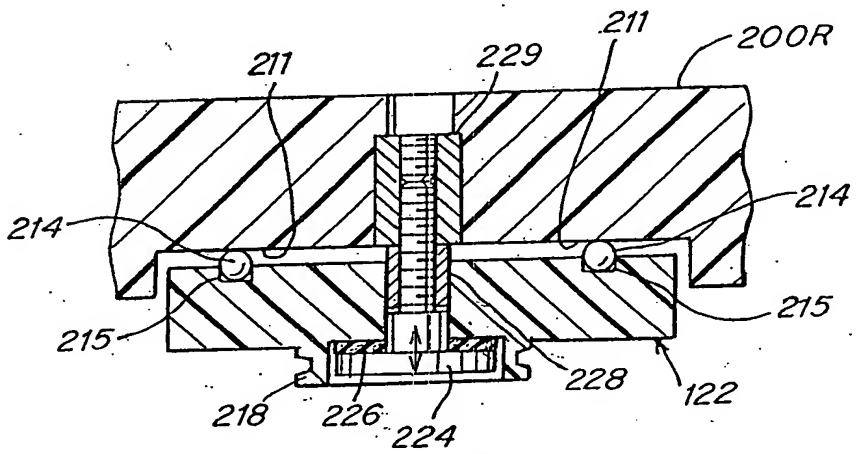
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Fig. 31

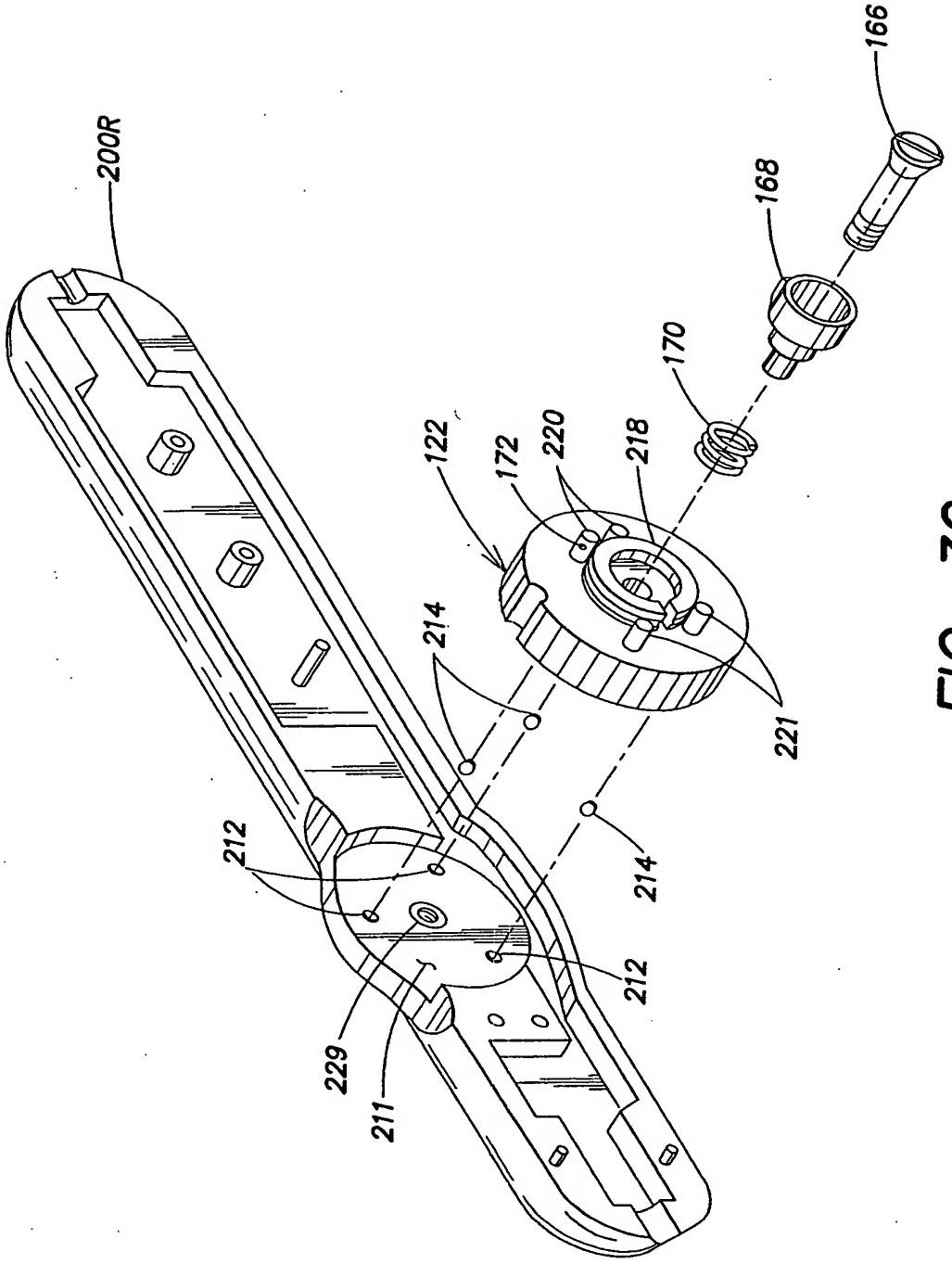

FIG. 32

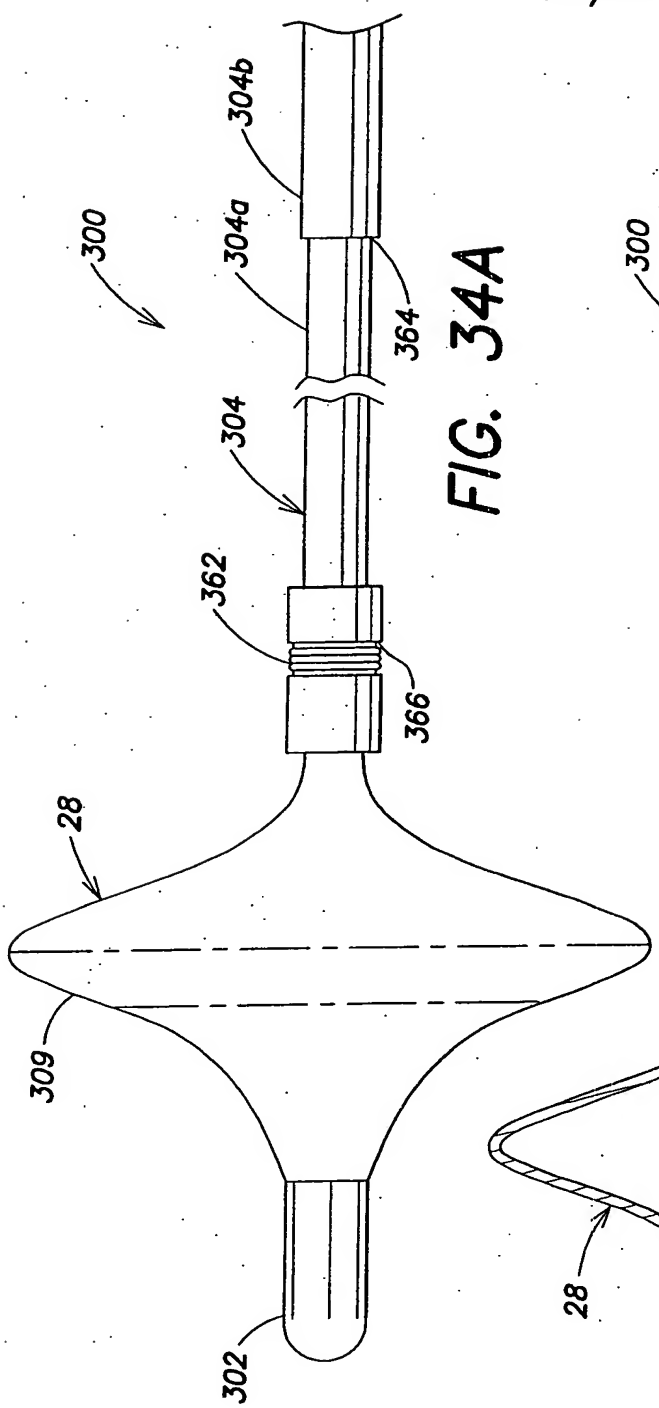

FIG. 34A

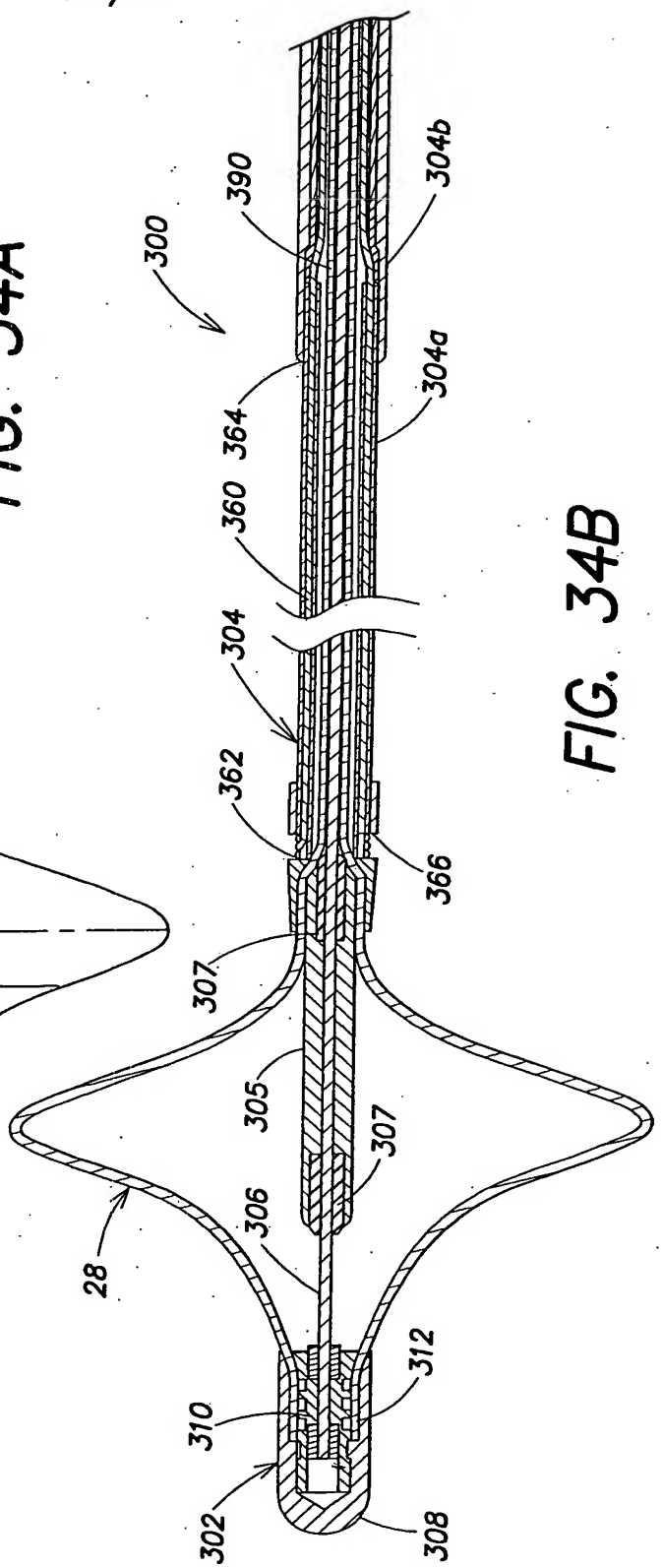

FIG. 34B

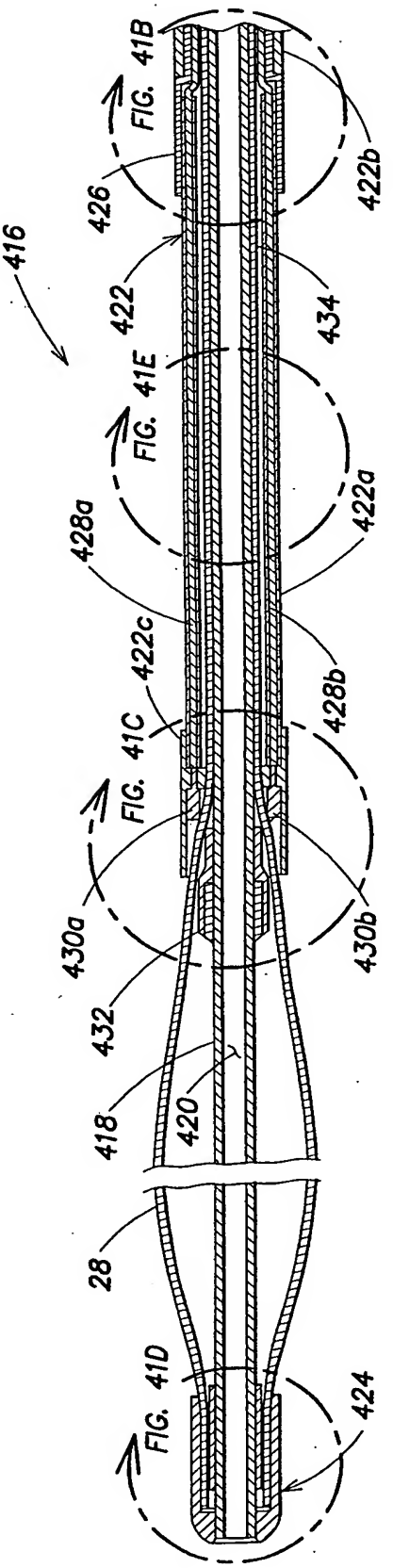
416
FIG. 41B
426
422b
422
434
FIG. 41E
428a
422a
422c
428b
FIG. 41C
430a
430b
432
418
420
28
FIG. 41D
424

FIG. 41A